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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
9362-4

CERTIFICATION OF ELECTRONIC TRANSMISSION
UNDER 37 CFR § 1.8

I hereby certify that this correspondence is being transmitted electronically to the U.S. Patent and Trademark Office on August 1, 2006.

Ehri A. Campion
Date of Signature: August 1, 2006

Application Number	Filed
10/662,621	September 15, 2003

First Named Inventor
Michael S. Williams

Art Unit	Examiner
9764	Neil S. Levy

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 48,568

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Needham James Boddie, II
Typed or printed name

(919) 854-1400
Telephone number

August 1, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

RESPONSE UNDER 37 C.F.R. 1.116 - EXPEDITED PROCEDURE - EXAMINING GROUP 1615

Attorney Docket No. 9362-4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Williams *et al.*
Application Serial No.: 10/662,621
Filed: September 15, 2003
For: **CARBON DIOXIDE-ASSISTED METHODS OF PROVIDING BIOCOMPATIBLE INTRALUMINAL PROSTHESES**

Confirmation No. 9764
Group Art Unit: 1615
Examiner: Neil S. Levy

Date: August 1, 2006

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REASONS FOR SECOND PRE-APPEAL BRIEF REQUEST FOR REVIEW

This document is submitted in support of the Second Pre-Appeal Brief Request For Review filed concurrently with a Second Notice of Appeal for the above-referenced patent application. No amendments are being filed with this Request.

If any extension of time for the accompanying response or submission is required, Applicants request that this be considered a petition therefor. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to Deposit Account No. 50-0220.

REMARKS

Applicants hereby request a second Pre-Appeal Brief Review of the finally rejected claims. This request describes the reasons for which the pending rejections should be withdrawn and briefly outlines the prosecution history of the above-referenced patent application since the filing of the first Pre-Appeal Brief Request For Review of August 19, 2005.

A. Non-Final Office Action of September 15, 2005

In a non-final Office Action (the "9-15-05 Action"), mailed September 15, 2005, Claims 1-14 and 16-26 were pending. Claims 1-14 and 16-26 were rejected under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over, U.S. Patent No. 6,071,439 to Bawa et al. ("Bawa"). In addition, Claims 2-14 and 16-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication No.

2003/0044514 to Richard ("Richard") and European Patent Application No. 0405284 ("Greiner") in view of "Active growth factor delivery from poly(D,L-lactide-coglycolide) foams prepared in supercritical CO_2" by David D. Hile *et al.* ("Hile") or Bawa. The 9-15-05 Action stated that Applicants' amendment of June 23, 2005 had been entered.

B. Response to 9-15-05 Action

In a Response transmitted to the Examiner via facsimile transmission on December 13, 2005, Applicants amended independent Claims 1 and 15 and dependent Claim 23.

C. Office Communication of March 21, 2006

In an Office Communication, mailed March 21, 2006, the Examiner stated the following:

> Examiner suggests amending the current December 12 amendment, which as following a non-final action, has been entered, reflecting that claims 1 & 15 are cancelled, as are 10, 22 & 26, but keeping the same subject matter, as ***these claims now are seen as non-obvious & novel over the rejections of record.*** ***Alternatively, the claims could be re-numbered, starting with 27.***

D. Response to Office Communication of March 21, 2006

In a Response transmitted to the Examiner via facsimile transmission on March 27, 2006, the pending claims, numbered as 1-9, 11-21, and 23-25 in Applicants' Response to Office Action of September 15, 2005, dated December 13, 2005, were renumbered as new Claims 27-49 pursuant to the Examiner's suggestion. Claims 1-26 were cancelled.

E. Final Office Action of June 16, 2006

In a final Office Action (the "Final Action"), mailed June 16, 2006, the Examiner has rejected Claims 27-45 and 47-49; the very claims indicated as non-obvious and novel in the Office Communication of March 21, 2006. Specifically, Claims 40-45 and 47-49 were rejected under 35 U.S.C. §103(a) as being obvious over Bawa. Claims 27-45 and 47-49 were rejected under 35 U.S.C. §103(a) as being unpatentable over Richard and Greiner in view of Hile or Bawa.

Applicants, pursuant to the Examiner's own suggestion, have renumbered claims already indicated as non-obvious and novel over these very same references. Moreover, the Final Action

is the **third time** during prosecution of the above-referenced patent application that the Examiner has indicated that claims are allowable, has suggested that they be renumbered or rewritten in independent form, and then has subsequently and arbitrarily rejected the very same claims.

Applicants' independent Claim 40 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use, comprising:

> providing an intraluminal prosthesis having a portion thereof formed from erodible polymeric material selected from the group consisting of: surgical gut, silk, cotton, ..., wherein the polymeric material contains one or more toxic materials;
>
> immersing the polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, wherein pressure and/or temperature of the densified carbon dioxide composition is adjusted to selectively absorb toxic materials from the polymeric material;
>
> removing the densified carbon dioxide composition containing the toxic materials from the polymeric material;
>
> lowering the density of the removed densified carbon dioxide composition such that the toxic materials entrained therein become separated therefrom; and
>
> removing the separated toxic materials, such that the intraluminal prosthesis is suitable for *in vivo* use.

Bawa describes a method of treating contact lenses made from polymerizable materials by providing supercritical fluids to the lenses. (Bawa, Abstract). Bawa fails to describe an intraluminal prosthesis having a portion formed from erodible polymeric material. Bawa describes soft contact lenses that include hydrogel contact lenses. Nothing in Bawa, however, describes contact lenses formed from erodible material. In fact, a passage in Bawa specifically states that "hydrogels are hydrophilic polymers that absorb water to an equilibrium value and are ***insoluble*** in water due to the presence of a crosslinked three-dimensional network." (Bawa, Col. 3, Lines 15-18). Clearly hydrogels are not erodible if they are insoluble in water. A thorough search of the remainder of Bawa failed to locate a single instance of the word "erodible." Moreover, Applicants respectfully assert that one skilled in the art would not manufacture contact lenses from polymeric material that is erodible when in use (*i.e.*, when worn by a person), as this would affect the vision of the wearer, thus destroying the intended purpose of the contact lenses. Moreover, some eroded material may remain in the wearer's eye, which would be most undesirable. Bawa also fails to describe immersing polymeric material in a

densified carbon dioxide composition such that the toxic materials are absorbed by the densified carbon dioxide composition, or pressure and/or temperature of the densified carbon dioxide composition being adjusted to ***selectively absorb*** toxic materials from the polymeric material.

Applicants' independent Claim 27 recites a method of producing a biocompatible intraluminal prosthesis for *in vivo* use, comprising:

> providing an intraluminal prosthesis having a portion thereof formed from polymeric material, wherein the polymeric material contains one or more toxic materials;
> masking one or more portions of the polymeric material;
> immersing the polymeric material in a densified carbon dioxide composition such that the toxic materials are absorbed from unmasked portions of the polymeric material by the densified carbon dioxide composition; and
> removing the densified carbon dioxide composition containing the toxic materials from the polymeric material, such that the intraluminal prosthesis is suitable for *in vivo* use.

The 9-15-06 Action conceded that Richard fails to disclose "attendant toxics, or cosolvents, or masking." (9-15-06 Action, Page 4). Greiner describes a method of impregnating a catheter, made of polymeric material, with a pharmaceutical. Greiner fails to teach or suggest immersing a polymeric material in a densified carbon dioxide composition such that toxic materials are ***absorbed*** by the densified carbon dioxide composition. Greiner fails to teach or suggest masking one or more portions of polymeric material of a catheter and impregnating only unmasked portions thereof. Hile describes a method, using supercritical carbon dioxide, for the production of microporous copolymer foams containing encapsulated proteins. Hile fails to teach or suggest immersing polymeric material in densified carbon dioxide such that toxic materials are ***absorbed*** by the densified carbon dioxide. Hile fails to teach or suggest masking microporous copolymer foams during the production thereof and removing toxic materials only from unmasked portions of the foams.

The combination of Richard, Greiner and Hile fails to teach or suggest all of the recitations of Applicants' independent Claims 27 and 40. Richard, Greiner and Hile all fail to teach or suggest: masking polymeric material and removing toxic materials only from unmasked portions; and immersing a polymeric material in a densified carbon dioxide composition such that toxic materials are ***absorbed*** (or selectively absorbed) by the densified carbon dioxide composition. In fact, Hile teaches away from the absorption of toxic materials by describing

removing methylene chloride from polymeric material by forcing out the methylene chloride under pressure. Hile does not teach or suggest that the methylene chloride is absorbed by the CO_2.

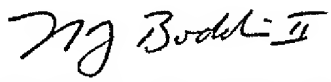
The combination of Richard, Greiner and Bawa also fails to teach or suggest all of the recitations of Applicants' independent Claims 27 and 40. As described above, Bawa fails to describe: ***masking*** one or more portions of polymeric material; an intraluminal prosthesis having a portion formed from ***erodible*** polymeric material; selectively absorbing toxic materials from polymeric material by adjusting pressure and/or temperature of densified carbon dioxide.

CONCLUSION

Applicants submit that the Examiner erred in rejecting the renumbered claims that were submitted in the Response of March 21, 2006. Applicants have tried numerous times during prosecution of the above-referenced patent application to amend and/or renumber claims indicated as being allowable by the Examiner pursuant to the suggestion of the Examiner, only to have the very same claims subsequently rejected.

Applicants submit that the present application is not in condition for appeal because of clear error on the part of the Examiner, and request that the application be passed to issuance based on the amended claims in the Response of March 21, 2006.

Respectfully submitted,



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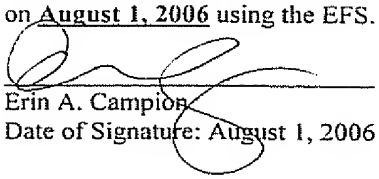

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Date of Signature: August 1, 2006